IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 4025**
Toshitada NOGUCHI et al.	:	Attorney Docket No. 2005_0034A
Serial No. 10/521,576	:	Group Art Unit 1651
Filed June 29, 2005	:	Examiner Kade Ariani
PROCESS FOR PRODUCING CMP-N-ACETYLNEURAMINIC ACID	:	**Mail Stop: AF**

DECLARATION UNDER 37 C.F.R. ' 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Tomoki HAMAMOTO, the undersigned, a citizen of Japan, residing at 1361-1, Room 102, Sakae-cho 2-chome, Choshi-shi, Chiba, Japan, do hereby declare:

1. That I am an inventor of the above-identified application,

2. That I graduated from Tokyo University of Agriculture and Technology in 1992 with a degree in Bioscience,

3. That since 1992 I have been working as a researcher at Yamasa Corporation, and

4. That I have carefully reviewed the file history and application of Application No. 10/521,576.

Attachment A

In particular, I have noted the obviousness rejection over Koizumi et al. (US 2002/0064836) in view of Plumbridge & Vimr (Journal of Bacteriology, 1999), and further in view of Tabata et al. (Enzyme & Microbial Technology, March 2002), and further in view of IUBMB enzyme nomenclature (EC 5.9.3.1).

It is my professional opinion and belief that a person of skilled in the art would not be motivated to combine these references to arrive at the invention of claims 2 and 5 or the dependent claims. In particular, as noted in the attached publication (Hamamoto et al., "Enzymatic Synthesis of Cytidine 5'-Monophospho-*N*-acetylneuraminic Acid", Boisei. Biotechnol. Biochem. 69 (10), pt. 1944-1950, (2005)). It was necessary to engage in undue experimentation in order to arrive at the claimed invention. For instance, we have first attempted to use NanA and NanE of *H. influenzae* for synthesis of NeuAc from GlcNAc and examined NeuAc synthesis with *E.coli* cells producing both enzymes. Such did not result in efficient production of CMP-NeuAc. We further had to use a number of different *E.coli* strains to find a suitable host for NeuAc synthesis. Also, we attempted to use glucokinas from *bacillus subtills*. Additional experiments were also performed as shown on page 1949 of the attached reference.

Thus, as shown in the attached reference, it was necessary to engage undue experimentation to arrive at the claimed invention. Thus, as noted previously, the claimed method of efficient production is only obtained by the exact combination of components as shown in claims 2 and 5. Other combinations, as shown in Hamamoto et al., did not result in efficient production.

Thus, it is my expert opinion and belief that there is no reasonable expectation of success based on the references cited in the Office Action dated December 10, 2008 to arrive at the claimed invention. It is therefore my expert opinion and belief that the claimed invention is not rendered obvious by the cited references as there is no motivation for their combination.

I further declare that all statements made herein of my own knowledge are true

and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Date: March 30, 2009

Tomoki Hamamoto

Tomoki Hamamoto